Advice on NIH SBIR & STTR Grant Applications
Small Business Funds for Academic Investigators

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Hello, I am Gregory Milman. In these presentations I provide advice on the NIH SBIR and STTR programs. This module is Small Business Funds for Academic Investigators . It was updated in July 2009. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.

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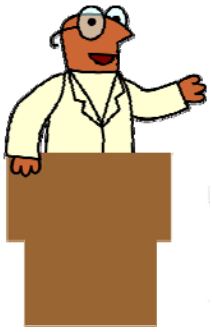
Agenda
Academics Can Benefit from Small Business Funds



- Ways academics can tap into SBIR & STTR grants
- Award rate comparisons
- Academic/company cultural divide
- Reasons academics start companies
- Steps to start-ups
- Gain access to intellectual property
- Resources for start-ups
- Return-on-investment (ROI) considerations
- Required company credentials

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Agenda - Starting Your Company

This module is for academic researchers who seek funding for their laboratories or translational research opportunities. By collaborating with small businesses on NIH SBIR or STTR awards, academic researchers can receive funds comparable to those for R01 research grants and at a better success rate. For successful collaboration, you should understand the cultural divide that separates non-profit academic from for-profit research.

Academic researchers can also start companies using NIH small business funds. First, you obtain access to intellectual property, usually your own inventions patented by your academic institution. Next, you decide on a product and identify resources for its development and apply for SBIR or STTR funds. Your application should contain a credible return-on-investment (ROI) strategy to assure business reviewers that your company is for-profit. Mentors can help you with start-up decisions, identify service groups, and obtain company credentials.

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Ways Academics Can Tap Into SBIR and STTR Grants

- Consultant on small business grant
- Subcontractor on small business grant
- Principal investigator on small business grant
  - Contact PI on STTR grant
  - Non-Contact PI on Multiple PI SBIR grant
- Start a small business with grant funds

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Ways Academics Can Tap Into SBIR and STTR Grants

Academic investigators can tap into SBIR and STTR funds in a number of ways. You could serve as a consultant on a small business grant retaining the consultant fee on top of your academic salary. Or, your laboratory could serve as a subcontractor on a small business grant. You could also be the contact PI on an STTR grant or a non-contact PI on a multiple PI SBIR grant. Finally you could start your own company with one or more small business grants.

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Potential NIH Subcontractor Total Cost Funds per Project

Grant	Years	per Year	Total	Subcontract
Phase I	2	$300K	$600K	~$300K
Phase II	3	$1,000K	$3,000K	~$1,500K
Renewal Phase II	3	$1000K	$3,000K	~$1,500K
Total	8		$6,600K	~$3,300K
Average			$825K	~$413K

FY2008 average 1R01 = $393K/year (Total Cost)

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Potential NIH Subcontractor Total Cost Funds per Project

This table shows how your laboratory could benefit from being a subcontractor on an SBIR or STTR grant.

For simplicity, I have assumed the subcontract is 50% of the small business grant. A 50% subcontract is more than "normal" for an SBIR Phase but within the realm of possible funding. It is also allowed for SBIR Phase II and STTR applications. A two year Phase I at $300K per year, a three year Phase II at $1M per year, and a 3 year Phase II renewal at $1M per year provides a total of $6.6M. $3.3M of that could go to the academic subcontractor over the eight years of the grants which gives an average of $413K per year. This subcontracted amount compares favorably with an FY2008 average competitive basic science R01 application that received an average of $393K/year total cost.

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Comparison of FY2008 NIH Award Rates

Type	Received	Funded	Award Rate
SBIR Ph I	3062	739	24.1%
SBIR Ph II	675	269	39.9%
STTR Ph I	805	109	13.5%
STTR Ph II	130	43	33.1%
R01	30624	5852	19.1%

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Comparison of FY2008 NIH Award Rates

This table shows the award rates (percent funded) of small business applications compared to R01 applications. The SBIR Phase I and II award rates of 24% and 40% compare favorably with the average NIH R01 award rate of 19%. Many ICs have even lower R01 award rates. The bottom line is that an academic laboratory can tap into SBIR grant funds comparable in dollars to R01 grants at an award rate better than that for R01 applications.

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Crossing the Academic–Company Cultural Divide

University	Company
Open Ended	Goal Oriented
Research	Development
Unpredictable	Specific Objectives
Easily change direction	Critical path
No promises	Milestones
Long Term Oriented (Career)	Funding Cycle (year)
Individual Controls	Company Controls
Individual (Principal Investigator)	Hierarchical (Team)
Openness and Publication	Confidentiality and Patents
Societal Responsibility	Proprietary Financial Gain

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Crossing the Academic–Company Cultural Divide

It is difficult for an academic investigator to cross the university/company cultural divide. This table summarizes some of the obvious differences that are often roadblocks to collaboration. First, academic research is open ended. Investigators often pursue a single research area their entire career. Successful companies focus efforts on producing a product ASAP. Second, academic research is unpredictable; investigators have freedom to change directions; time frames are not promised, and Specific Aims may not be achieved. Companies must set and achieve milestones for continued funding, and must control product development and capital burn rate. Third, academics thrive on openness, publication, and benefits to science and society. Companies require confidentiality, IP protection, and financial gain.

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Reasons Academic Faculty Start a Company

- Challenge
- Translational research – lab bench to product
- Patent ownership and promotion
- Potential financial reward
- Increase research funding
- Create jobs for graduate students & postdocs
- Career change

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Reasons Academic Faculty Start a Company

Academic faculty start companies for many reasons including the challenge of launching a new endeavor, and the opportunity to translate research into products. Patents and venture funding nourish one's ego and potentially offer a financial reward. Companies offer another source of research funding and can create jobs for graduate students and postdocs. Sometimes academic faculty decide to pursue the challenges of a business career in addition to or as a replacement of their academic careers.

In the next few slides, I provide advice on how to start a company using SBIR and STTR funding.

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Seven Steps for SBIR and STTR Startups

One, you need exclusive license to intellectual property for your core technology, usually patents.

Two, decide on the first product you will develop. This is often the most difficult decision because successful companies use core technology to produce a number of products. Among all the products you could develop, identify the most significant and innovative one. Review the "Background and Significance" slide in the "Writing for Reviewers" presentation and conduct basic market research.

Three, identify the space, equipment, personnel and collaborator resources needed for product research and development.

Four, prepare a chart with milestones, timelines, and funding necessary to develop your product to the stage where you will obtain an ROI, in other words, your exit strategy.

Five, ROI could come from commercialization, spin-off, merger and acquisition, or stock offering. To be credible, you should make your best estimate early even if later you change your mind.

Six, after completing the first five steps, decide whether to invest the time and effort to obtain company credentials that will enable you to apply for SBIR/STTR funds. Seek mentoring from businessmen, lawyers, accountants, and government SBIR/STTR staff.

Seven, review all my presentations and write your SBIR or STTR applications to appeal to reviewers.

Celebrate when you get an award, but be aware that the hard work is just beginning.

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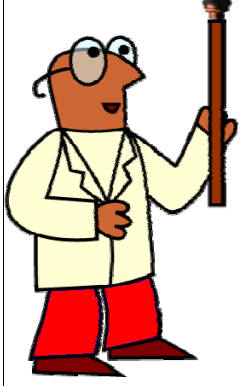
Inventions Resulting from U.S. Government Supported Research



- The Bayh-Dole Act specifies invention reporting compliance responsibilities and timelines.
- Your institution must report an invention to the U.S. funding agency within two months of learning about it from the inventor.
- iEdison (Interagency Edison) helps you meet these requirements.
- NIH may pursue a patent application if your institution elects not to.
- You may pursue a patent application if you request it and both your institution and NIH elect not to pursue it.

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Inventions Resulting from U.S. Government Supported Research

Your academic institution has potential rights to whatever you invent while you're employed. However, you still may be able to obtain exclusive rights to your discoveries.

The Bayh-Dole Act requires that institutions report all potential inventions arising from government supported research on iEdison and decide in two years or less whether or not to pursue a patent application. Report inventions to your institution as soon as possible to start the clock. Appeal to your institution to file a patent application promptly. You will force a patenting decision if you inform your technology transfer office that you plan to describe your discoveries in a public presentation or publication. Request an exclusive license to the patent if you want to use it to start a company.

Your institution may elect not to retain title if commercialization seems unlikely or if a licensee is not found that is willing to cover legal and patent costs. NIH then has the option of pursing the patent but usually does not. If neither your institution nor NIH elects to pursue a patent, you may retain ownership and file the patent application.

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Protect Intellectual Property

- Do not submit a grant application until you have applied for patents on your intellectual property.
- Obtain exclusive license to patents on your technology owned by your academic institution, or
- Obtain your academic institution's permission for you to patent your technology.
- The Bayh-Dole Act requires your institution to allow the inventor to pursue a patent if it elects not to.
- Provisional patents provide protection for one year at for a fee of $110 in 2009.
- Do not use a provisional filing when the value of the invention is clear and you have funds for a formal patent application.

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Protect Intellectual Property

I strongly recommend that you protect your intellectual property before you describe it in a grant application. I would not depend upon confidentiality agreements signed by reviewers or the fact that grant applications are not public documents.

Patent protection is an absolute requirement to obtain private funds for commercialization. Although it can take considerable time for a patent to be issued, at a minimum your inventions should be protected by Patent Pending or Provisional Patent Pending.

If the intellectual property belongs to an academic institution, you should insist that the institution file the patent application before you submit your grant application.

Also, if the intellectual property is owned by an academic institution, it is important to sign an exclusive license to commercialize it before developing it further. This is not an SBIR/STTR requirement. It is just good business sense.

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Resources

- Facility options
  - Discuss availability and lease terms for a 100-200 sq ft laboratory in your academic institution.
  - Investigate biotechnology incubator facilities in your area.
  - Examine availability and lease terms for a 100-200 sq ft laboratory in more established biotechnology companies in your area.
- Equipment
  - Availability included in lease
  - Purchase required
- PI and collaborator options (credible CVs)
  - You or academic colleagues
  - Research associate
  - Senior postdoctoral fellow

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Resources

You need to line up a number of resources for your new company but I suggest you arrange not to pay for them until you receive funding.

A tentative lease is necessary to convince reviewers you have the facilities to conduct your research. Discuss availability and lease terms for a lab in your academic institution, in a start-up incubator, or in a more established biotechnology company in your area. Be sure to discuss shared equipment and facilities that will strengthen the research and environment section of your grant application. Ideally, you should obtain access in your lease agreement to expensive equipment and unique facilities such as animal rooms, cold rooms, and ultracentrifuges. If you need to buy an expensive piece of equipment, see if you can obtain it through a lease-purchase agreement.

You also need to identify staff with credible CVs for the proposed research even if you know you will make changes when you receive an award. Academic collaborators with strong credentials can bolster your application if, and only if, they have specific duties and responsibilities. Many applications benefit by having a biostatistician on board to validate sample size, power of studies, and statistical significance or results.

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Investment Strategies

Return on Investment (ROI)

1. Commercialize – sell product
2. Spin-Off – license product development or sales
3. M & A – acquired by or merged with another company
4. Go public – sale of stock

Type of Company	Exit Strategy	Product Funding
■ Tools	Usually remain independent	$K to $M
■ Medical devices	Commercialize, Spin-Off, M&A	$K to $M
■ Diagnostics	Spin-Off, M&A	$K to $M
■ Vaccine	M&A, Stock	$M to $B
■ Drug	M&A, Stock	$M to $B

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Investment Strategies

Describing your investment strategy will enable reviewers to assess whether you have a realistic approach to a profitable business. For example, a start-up company that proposes to develop and market a new drug would not be credible because of the extensive cost and experience necessary to succeed.

Four ways for you and your investors to realize an ROI are (1) commercialize – your company makes and sells a product, (2) spin off – your company adds sufficient value to a potential product so it can license it to another company for further development and sales, (3) M&A – your company is merged with or acquired by another company, and (4) go public – your company has an initial public offering (IPO) of stock.

This table illustrates common exit strategies for different types of companies and the total cost to bring their products to market. Tools are widgets that one company independently sells to other companies or researchers. Medical device companies may commercialize their products, be spun-off, or be acquired by another company. Diagnostic companies usually require a large sales force so they do not commercialize their products. Their exit strategy is a spin-off or M&A. Due to the high cost of clinical trials, vaccine and drug companies will almost always go through M&A even if they first sell stock to the public.

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Company Credentials
About $500 - $1000

- Mentors through SCORE mentor (http://www.score.org) (Counselors to America's Small Business) and local economic development organization.
- Lawyer
- Accountant
- Incorporate for liability protection
  - Decide S corporation, limited liability company (LLC), C corporation
  - State incorporation and foreign state registration
- Obtain "Employer ID Number" (EIN)
- Obtain bank account
- Obtain "Data Universal Number System" (DUNS)
- Register with Central Contractor Registration (CCR) for Federal Government, Grants.gov and the eRA Commons
- Follow the NIH Electronic Submission of Grant Applications pathway.

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Company Credentials

For about $500 - $1000 you can obtain company credentials that will enable it to apply for federal grants. Of course you can pay more and maybe less. A place to start is with a SCORE mentor who can help you make business decisions. You can also seek help from your local economic development organization. You also need a lawyer, an accountant, and a business bank account. For liability protection, discuss and decide if you should be an S corporation, a limited liability company, or a C corporation, and in which state (e.g., Delaware) you should incorporate your company even if your company will primarily do business in your home state. Next, obtain an EIN, a business bank account, and a DUNS number. Then register with the Federal Government CCR and with the eRA Commons. Allow at least a month to complete all registrations before you submit a grant application. And, submit a first time application a month before a receipt date to allow sufficient time for you to correct errors before the deadline.

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More Presentations

TOPICS

- Basic Information
- Managing the NIH Timeline
- Writing for Reviewers
- FY2008 Data
- Tips and Tricks
- More than SBIR/STTR Funds
- Small Business Funds for Academic Investigators

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Thank you for watching this module. Close this window to select another topic.